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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,266	11/30/2001	Felix Kratz	NY-HUBR 1198	1297
24972	7590	05/18/2004	EXAMINER	
FULBRIGHT & JAWORSKI, LLP			TELLER, ROY R	
666 FIFTH AVE			ART UNIT	
NEW YORK, NY 10103-3198			PAPER NUMBER	

1654

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/980,266

**Applicant(s)**

KRATZ, FELIX

**Examiner**

Roy Teller

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 39-57 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 39-57 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

This office action is in response to Applicant's communication, received 3/2/04, in which applicant cancelled claims 20-38 and added new claims 39-57.

Claims 39-57 are pending.

#### ***Claim Objections***

Claims 55-57 are objected to because of the following informalities: Claims 55-57 depended upon cancelled claims 35 and 37. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

The rejection under 35 U.S.C. 112, second paragraph of claims 39, 49, 50, and 54 is maintained.

Claims 39, 49, 50 and 54 stand/are rejected under 35 U.S.C. 112, second paragraph for the reasons set forth in the previous office action which are restated below:

Claims 39, 49, 50, and 54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 39, 49, and 50 recite a spacer, this is vague and indefinite for failing to define the metes and bounds of the spacer.

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Claims 39 and 54 recite a protein-binding molecular residue, this is vague and indefinite for failing to define the metes and bounds of the protein-binding residue.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also rejected under U.S.C. 112, second paragraph for reasons set forth above.

Applicant's arguments were carefully considered but were not found persuasive.

Applicant contends that the term "spacer" and "protein binding molecule" is defined in the instant specification. The Examiner agrees, but the Examiner cannot read limitations into the claims from the specification. The claims must be interpreted from the claim language. Applicant points to claims 44 and 45, which point to preferred "spacers" and "protein binding molecules". The Examiner suggests incorporating claims 44 and 45 into the independent claims to further define the invention and overcome the rejection.

### ***Claim Rejections - 35 USC § 102***

The rejection under 35 U.S.C. 102(b) of claims 39-57 is maintained.

Claims 39-57 stand/are rejected under 35 U.S.C. 102(b) for the reasons set forth in the previous office action which are restated below.

Claims 39-57 are rejected under 35 U.S.C. 102(b) as being anticipated by Trouet, Proc. Natl. Acad. Sci. USA Jan. 1982, Vol. 79, pp. 626-629.

The instant invention is drawn to a method for producing injectable medicament preparations containing a therapeutically and/or diagnostically effective substance which is comprised of an active agent, of a spacer molecule and of at least one protein-binding molecule.

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Trouet teaches Daunorubicin (DNR) conjugated to succinylated serum albumin by an amide bond joining the amino group of the drug and the carboxyl side chain of the protein either directly or with the intercalation of a peptide spacer arm varying from one to four amino acids (see abstract). Trouet discloses that the use of a spacer is essential to obtain DNR-protein conjugates that remain stable in serum and from which DNR can be released through the action of lysosomal hydrolases (see abstract). Trouet teaches that DNR is released intracellularly after digestion by lysosomal enzymes (see abstract). Trouet discloses that this method can be applied to other drugs and various potential carriers, such as antibodies, polypeptide hormones, and glycoproteins (see abstract).

Applicant contends that the Trouet reference is different than the claimed invention. The Examiner points out that the independent claims of the instant invention do mimic the components of the Trouet reference and the claims of the instant invention do not separate themselves from the prior art. The examiner suggests incorporating elements of the dependent claims into the independent claims to define Applicant's invention away from the prior art.

### ***Conclusion***

All claims are rejected.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is 571-272-0971. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on 571-272-0971. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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CHRISTOPHER R. TATE  
PRIMARY EXAMINER